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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,091	12/16/2004	Giancarlo Cravotto	48239	5511

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EXAMINER

CARR, DEBORAH D

ART UNIT	PAPER NUMBER
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1621

DATE MAILED: 02/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/518,091	Applicant(s) CRAVOTTO, GIANCARLO	
	Examiner Deborah D. Carr	Art Unit 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 13-15 and 19 is/are allowed.
- 6) ☒ Claim(s) 1-12, 16-18 and 20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/16/04</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12, 20 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant specification is not seen to provide adequate guidance, which would allow the skilled artisan to extrapolate from the same to establish enablement for the preparation of pharmaceutically or nutraceutically effective compositions.

There is not seen sufficient guidance, which would teach the skilled artisan how to make said pharmaceutically or nutraceutically effective compositions nor administer said compositions in such a way they would be deemed effective in methods for preventing or treating any diseases. There are no working examples set forth in the instant specification limited to the process for preparing the instant compositions.

Nor are there any examples drawn to the treatment or prevention of a clinical condition for which the pharmaceutically or nutraceutically effective compositions are

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indicated and there is not seen sufficient correlative data to substantiate the preventive efficacy of any of the pharmaceutically or nutraceutically effective compositions set forth in the instant disclosure.

2. Claims 2-3 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for diabetic peripheral neuropathy, does not reasonably provide enablement for all peripheral neuropathies or vascular diseases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Peripheral neuropathies or vascular diseases can be caused by various reasons such as hereditary disorders, systemic or metabolic disorders, infectious or inflammatory conditions, and exposure to toxic compounds, drugs or miscellaneous causes. Applicant's disclosure does not provide enablement for all of the cause for these two diseases.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-12, 16-18, 20 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is rendered indefinite by the preamble, "A method for preparing pharmaceutical or nutraceutical compositions useful for the preparation of pharmaceutical or nutraceutical compositions useful for the treatment and prevention of peripheral vascular diseases and peripheral neuropathies which comprise adding to said composition a compound..." It is unclear what applicant's is actually preparing.

Claim 17 is rendered indefinite by the phrase "corresponding primary alcohols and C1-C4 alkyl ester of these acids." Since claim 13 reads on primary alcohols, it is unclear what compounds applicants are referring to, the compounds on claim 13 or 17 listed supra this phrase. Also claim 18 reads on "in the form of ester" referring back to claim 17. Are they esters of claim 13 or claim 17?

5. Claims 9-11 recites the limitation "R2 = R1-X" in line 2. There is insufficient antecedent basis for this limitation in the claim. Claim 1 does not contain a "R2" moiety in the defining of the compound of the formula R-X.

6. Claim 16 recites the limitation "compounds of claim 12" in line 1. There is insufficient antecedent basis for this limitation in the claim. Claim 12 reads on a method not a compound.

7. Claims 1-12, 20 rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP

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§ 2172.01. The omitted steps are: the actual process steps used to prepare the pharmaceutically or nutraceutically effective compositions..

8. Regarding claim 4, the phrase "in particular" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1, 8 rejected under 35 U.S.C. 102(b) as being clearly anticipated by JP-60/218328.

JP'328 teaches the instant invention when R = 24 carbons, saturated and X = -COOH (RN:100754-13-0) and are used in pharmaceutical compositions.

Allowable Subject Matter

11. Claims 13-15, 19 are allowable over the prior art.

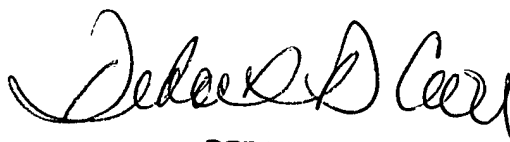
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah D. Carr whose telephone number is 571-272-0637.

The examiner can normally be reached on Monday-Friday 8:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



DEBORAH D. CARR
PRIMARY EXAMINER

ddc